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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/716,314 STEWART ET AL. Office Action Summary Examiner Art Unit AGNES B. ROOKE 1656 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 10 December 2007. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 23.24.32 and 34-40 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 23.24.and 32 34-39 is/are rejected. 7) Claim(s) 40 is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

PTOL-326 (Rev. 08-06)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

Paper No(s)/Mail Date 12/10/2007

Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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DETAILED ACTION

This FINAL office action is in response to the paper filed on 12/10/2007. The amendments to the claims and specification submitted on 12/10/2007 are acknowledged.

Status of Claims

Claims 23, 24, 32, 34-40 are pending and under examination. Claims 1-22, 25-31, and 33 are canceled.

New - Objection to Claims

Claims 38 is objected to for depending from Claim 1 because Claim 1 is cancelled. The claim should indicate the peptide of Claim 23.

Claim 40 is objected because it is cumbersome since it refers to "the mammal comprising a human." Examiner suggests that the claim be rewritten for clarity purposes, to say "the mammal is a human" for example.

New - Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites several different ranges of 90-100%, 95-100% and 99-100%. These are ranges within ranges and are unclear which are intended. Clarification is required.

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Maintained - Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Previous rejection of Claims 23, 24, 32, and 34 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained; Claims 35-38 and 40 are added to this rejection. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these (paraphrased from Enzo Biochemical Inc., v. Gen-Probe Inc. (CAFC (2002) 63 USPQ2d 1609).

University of Rochester v. G.D. Searle & Co. (69 USPQ2d 1886 (2004)) specifically points to the applicability of both Lily and Enzo Biochemical to methods of using products, wherein said products lack adequate written description. While in University of Rochester v. G.D. Searle & Co. the methods were held to lack written description because not a single example of the product used in the claimed methods was described, the same analysis applies wherein the product, used in the claimed methods, must have adequate written description as noted from Enzo Biochemical (see above).

In the instant case, the Applicants refer to a broad genus of variants of SEQ ID NO:2 (as any 10 amino acids of SEQ ID NO:2). The structures of the genus that are claimed are not

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sufficiently described because Applicants did not provide in the instant specification or claims any specific fragments of SEQ ID NO:2 that are at least 10 amino acids long that would retain paralytic activity.

Thus, one skilled in the art would be unable to determine, according to claim 23, what is the structure of these specific fragments i.e. at least 10 amino acids that retain paralytic activity of SEQ ID NO:2, and thus what is the function of these undefined fragments that comprise any 10 amino acids. Further, claim 23 uses an open language and thus the peptide used in the method can encompass any 10 amino acids of SEQ ID NO:2 and still expect to have the function of paralytic activity. Moreover, since the particular structure of these different fragments i.e 10 amino acids of SEQ ID NO:2 is not particularly disclosed, thus the function of these peptides cannot be ascertained, since any 10 amino acids of SEQ ID NO:2 that are incorporated in any peptide would not necessary retain the desired function of paralytic activity. Thus, the written description requirement is not satisfied because the structure of these 10 amino acid fragments does not necessary correspond with their function.

Applicants responded that claim 23 as amended presented a particular structure of a fragment of SEQ ID NO:2, where the full SEQ ID NO:2 is provided. Therefore, Applicants assert, there is clear direction and guidance in regards to how to identify fragments of SEQ ID NO:2 that would have the claimed paralytic activity. In addition, applicants refer to a mealworm assay that allows for determination of fragments having paralytic activity.

Examiner respectfully disagrees and states that Applicants did not adequately describe fragments that have at least 10 amino acids of SEQ ID NO:2 and would still retain paralytic activity. Even though SEQ ID NO:2 is composed of only 54 amino acids, there could be different

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combinations of at least 10 amino acids that do not necessary retain the paralytic activity function. Further, the mealworm assay does not discuss any particular fragments that would be relevant to paralytic activity. Thus, because the structure of these 10 amino acids fragments do not correspond with their function the written description requirement is not satisfied and the rejection is maintained.

Previous rejection of Claims 23, 24, 32, and 34 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the full length of the peptide of SEQ ID NO:2, does not reasonably provide enablement for at least 10 amino acids of SEQ ID NO:2 is maintained; further new Claims 35-38 and 40 are added to this rejection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) eight factors should be addressed in determining enablement.

- The nature of the invention: the instant invention refers to a method of providing analgesia or neuromuscular blocking comprising administering a peptide that contains at least 10 amino acids of SEQ ID NO:2 wherein the peptide has paralytic activity.
- 2) The breadth of the claims: the claims are extremely broad because they encompass any peptide that contains at least 10 amino acids of SEQ ID NO:2 that has paralytic activity and is administered to a mammal.
- 3) The predictability or unpredictability of the art: there is a great unpredictability in the art with regards to different variants of a peptide that has at least 10 amino acids of SEQ ID

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NO:2. Applicants on page 7, line 26 to page 8, line 6, describe different fragments of SEQ ID NO:2 that are significant for paralytic activity. However, no experiments or working examples are presented in the specification that would exemplify those fragments (for example at least 10 amino acids of SEQ ID NO:2) that would work for its intended purpose i.e. a paralytic activity). Thus, one skilled in the art would not know whether a fragment of at least 10 amino acids would actually work when administered to a mammal.

- 4) & 5) The amount of direction or guidance presented:/The presence or absence of working examples: there are no working examples in regards to at least 10 amino acids of SEQ ID NO:2. Therefore, specification, except describing relevant fragments on pages 7-8 of the disclosure, does not guide one skilled in the art what fragments work as to their paralytic activity and what fragments do not work, since no working examples are presented.
- 6) The quantity of experimentation necessary: there is a large quantity of experimentation necessary to determine which 10 amino acids of SEQ ID NO:2 when included in a peptide composition will retain the paralytic activity since no working examples are presented.
- The state of the prior art: the shrew toxin was isolated and purified and was administered to a mammal.
 - 8.) Level of skill in the art: the level of skill in this art is high.

There would be an undue experimentation to one skilled in the art to practice this invention when considering the totality of the Wands factors. Therefore, Applicants are enabled for the full length of SEQ ID NO:2 but are not enabled for different fragments of SEQ ID NO:2 that retain paralytic activity, since no support can be found in the working examples considering fragments of SEQ ID NO:2.

Applicants responded that one skilled in the art would be able to figure out which 10 amino acids of SEQ ID NO:2 have paralytic activity when mealworm assay on page 29, lines 1-4, is used.

Examiner responds that Applicants did not offer any working examples that would identify which 10 amino acid fragments of SEQ ID NO:2 have paralytic activity.

Next, Applicants argue that any experimentation to determine which fragments would have paralytic activity would be routine to one skill in the art, since SEQ ID NO:2 contains only 54 amino acids. Also, Applicants assert that they are only five 10-amino acid fragments in SEQ ID NO:2, and thus testing those fragments would be routine to one skill in the art.

Examiner responds that they are any 10 amino acid fragments in SEQ ID NO:2 that need to be investigated and thus the experimentation is undue because one skilled in the art would not know which particular fragment(s) of 10 amino acids must be used for experimentation and still retain desired function.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Previous rejection of Claims 23, 24, and 32 under 35 U.S.C. 102(b) as being anticipated by Bucherl et al., (Venomous Animals and Their Venoms, Vol. 1, Academic Press, 1968) is maintained; further Claims 35, 38 and 39 are added.

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On page 45, last paragraph, Bucherl et al. teach that the purified toxin was concentrated and with regards to mammals (i.e. rabbits), the lethal dose was determined. (See also Figure 2, on page 47). This toxin inherently includes the protein sequence of SEQ ID NO:2 of the instant claims, because the protein originates from the same source and has the same function.

Further, on page 46, third paragraph from the bottom, the effects of the venom of *Blarina* are discussed regarding changes in circulatory and respiratory systems of rabbits.

On page 48, second paragraph from the bottom, the effect of the venoms of shrews on experimental animals is discussed, such as paralysis of hind limbs and convulsions, where the intensity of reaction depended on the size of the dose and the site of administration, where the most effective were the intravenous injections of extract of the sublimary glands of Blarina.

Claims 23, 35, 38, and 39 are anticipated by Bucherl et al. who discuss the shrew toxin being administered to rabbits to affect the paralysis. The instant claims 23, 35, and 39 refer to a method of providing analgesia or neuromuscular blocking in a mammal comprising administration of a peptide that contain at least 10 amino acids of SEQ ID NO:2 where the peptide has paralytic activity. Thus, claims 23, 35, 38, and 39 are anticipated by the prior art because a fragment of SEQ ID NO:2 or SEQ ID NO:2 would be inherently present in the paralytic toxin from shrew that was discussed in Bucherl et al.

Also, claims 24 and 32 would be included in this rejection because analgesia or neuromuscular blocking are intended uses (claim 24) and the wild type peptide is the same as a synthetic peptide (claim 32).

Applicants responded that claim 23 has been amended to recite methods of using an "isolated" peptide. New claims 35-37 recite additional aspects of purity of the peptides in the Art Unit: 1656

methods. Further, Applicants state that Bucherl et al. do not teach an isolated peptide of SEQ ID NO:2 or its fragments or methods of using SEQ ID NO:2 for analgesia or neuromuscular blocking.

First, Applicants address the issue that Bucherl et al. do not teach an isolated SEQ ID NO:2 and that Bucherl et al. teach only that the toxin from the short-tailed shrew, *Blarina brevicauda* has been only partly determined and not precisely defined.

Examiner responds that the reference teaches that the toxin was purified (isolated from its natural environment) and that the lethal dose was determined, and thus the toxin inherently includes the protein and/or the fragment of SEQ ID NO:2.

Second, Applicants state that Bucherl et al. do not expressly or inherently disclose an isolated or purified compound with paralytic activity, and that the extract taught in the reference involves only a crude extract and that the mixture of compounds of submaxillary gland of Blarina that is an unknown mixture of proteins. Also, Applicants state that Bucherel et al. use the term "purified toxin" to refer to a homogenate that had only preliminary separation steps performed on it, not a purified polypeptide. Further, Applicants state that the term "purified" does not mean real purification and isolation since the term is used in quotation marks. In addition, Applicants state that the extracts disclosed in Bucherl et al. would include other toxic compounds and many other proteins or enzymes.

Examiner responds that the reference teaches that the toxin was purified and that the lethal dose was determined and thus the toxin inherently includes the protein of SEQ ID NO:2. Further, claims as presently have an open language "comprising" that would include other toxins or proteins that are included in the preparation that is administered to a mammal to cause

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paralysis. The art need not appreciate all the characteristics of the composition they used to treat, i.e., that is was proteinaceous.

Third, Applicants state that a peptide of SEQ ID NO:2 cannot be obtained merely by homogenizing and extracting the submaxillary gland since the peptide will still be in a large complex and thus inactive. Therefore, the peptide useful in the claimed methods cannot be obtained merely by homogenizing and extracting the submaxillary gland.

Examiner responds that in the absence of the specific facts to the contrary, the isolated extract from the saliva of the shrew will possess SEQ ID NO:2 or its fragments. Further, the extract was administered to mammals and caused paralysis, thus has paralytic activity. Further, Applicants claim the possession of at least 10 amino acids of SEQ ID NO:2, and thus such fragment is present in the toxin preparation of Bucherl et al.

Fourth, Applicants state that Bucherl et al. teach a toxin of high molecular weight since the reference refers to an observation that the active agent was probably a protein and because of the inability to dialyze, a larger protein, where the SEQ ID NO:2 is a small peptide of 6kDa.

Examiner responds that the purified toxin was concentrated and with regards to mammals the lethal dose was determined, and that the toxin inherently includes SEQ ID NO:2 or its fragments because the protein originates from the same source and also has the same function. Further, the language of claim 23 as presented, comprises other proteins and fragments since the language of the claim is open. In addition, the undefined 10 amino acids of SEQ ID NO:2 can be a part of a bigger protein, for example, As presented in claim 23.

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Finally, Applicants state that the isolation of SEQ ID NO:2 from large protein complex was unexpected and the complex is about 600kDa and that one would not expect the toxin to be a small peptide.

Examiner responds that the purified toxin of Bucherl et al. was purified from the same source as the instant invention and had the same paralytic activity. Further, the process of purification of SEQ ID NO:2 is not claimed, but instead a method of administering a composition that comprises SEQ ID NO:2 and/or its fragments (at least 10 amino acids) that has a paralytic activity is instantly claimed. Therefore, the invention is not novel.

Another argument presented by Applicants states that SEQ ID NO:2 is not necessarily present in shrew saliva. Thus, the prior art did not determine whether any of the compounds in their crude extracts actually leave the gland, enter the saliva and are injected into the bitten subject, since the reference of Bucherel et al. teach only examination of glands. Further, Applicants assert that they isolated the shrew's paralytic toxin, rather than glandular compound that has toxic effects. Further, Applicants discussed where the paralytic peptide is produced. See Remarks section, on page 13, second paragraph.

Examiner responds that as pointed out in the Remarks section, page 13, first paragraph, in Figure 6, Applicants analyzed the toxin of the invention from the submaxillary gland and shrew saliva. Also, Bucherl et al. analyzed the paralytic peptides from shrew gland. Thus, the paralytic peptide of Bucherl et al. and the instant invention is from the same source and has the same activity. In addition, examiner points out that the process of production of the SEQ ID NO:2 or it purification is not at issue, but what is claimed is a method of administration of a composition

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comprising SEQ ID NO:2 and/or its fragments (at least 10 amino acids) that causes paralytic activity, and those facts are taught in Bucherl et al.

The final Applicants' argument regarding the novelty rejection asserts that Bucherel et al. do not teach a method of analgesia or neuromuscular blocking. Applicants state that the reference does not teach that the SEQ ID NO:2 causes paralysis. Also, Applicants state that Bucherel et al. describe toxic lethal effects of administering crude extracts of shrew gland, and there is no disclosure that those extracts will produce therapeutic analgesia or neuromuscular blocking.

Examiner responds that analgesia and neuromuscular blocking are intended uses. The claim preamble must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works*, 868 F.2d at 1257, 9 USPQ2d at 1966. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"). See MPEP 2111.02 Effect of Preamble [R-3]. Therefore, the preamble

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refers to an intended use, and Bucherel et al. teach peptides that cause paralysis, thus having paralytic activity.

Therefore, the rejection is proper and is thus maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior at are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Previous rejection Claims 23 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bucherl et al., (Venomous Animals and Their Venoms, Vol. 1, Academic Press, 1968) in view of Kohane et al. U.S. 6,326,020 is maintained; further Claims 35-38 and 40 are added

The teachings of Bucherl et al. are discussed above where they do not teach a method of dosing a mammal in pain with highly purified protein.

Kohane et al. teach different nerve blockers that were used in animal models to make animals insensitive to pain. (See for example, column 6, lines 29-46 and claim 17 in column 23).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to design a method where the paralytic peptide as taught by Bucherl et al. is administered to a mammal to alleviate pain as taught by Kohane et al. Using purified peptides is

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an obvious variation of the prior art. Further, the outcome would be predictable from the data of Bucherl et al.

Applicants responded that there would be no reason or expectation of success in combining the teachings of Bucherl et al. and Kochane et al. to derive instant invention and those peptides provide unexpected and strong results in methods of analgesia and neuromuscular blocking. Further, Applicants assert that Kohane et al. teach small organic molecules that are different than proteinaceous toxins and that Kohane do not teach SEQ ID NO:2 or its fragments. Moreover, there would be no reason to combine these teachings and the prior art provides no suggestion that Kohane's compounds can be used to make animals insensitive to pain. Furthermore, on page 16 of the Remarks, Applicants discuss generally that the claimed compounds provide surprisingly strong results by producing a long lasting activity.

Examiner respectfully disagrees and points out that the instant invention only generally refers to "pain" that can mean any pain in a mammal. Further, Kohane et al. teach different nerve blockers that were used in animal models to make animals insensitive to pain, for example. The discussion above, regarding reference of Bucherl et al., clearly teaches administration of toxin that causes paralysis (where the toxin is a nerve blocker since it causes paralysis). Therefore, there is clear motivation to administer a paralytic peptide to subjects that suffer from any pain since a method such as this would be obvious in view of the prior art as cited above. One would be motivated to administer such paralytic peptides for generic pain since Kohane et al. clearly describes different nerve blockers that were used in animal models to make animals insensitive to pain, and to cause loss of sensation could mean paralysis of certain muscles stop nerve impulse transmission, for example.

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Therefore, the rejection is proper and is thus maintained.

Conclusion

No claims are allowed

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent

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system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

/Kathleen Kerr Bragdon/ Supervisory Patent Examiner, Art Unit 1656